Emergency Medical Services Focused Assessment with Sonography in Trauma & Cardiac Ultrasound (EMS-FOCUS)

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INTRODUCTION

Ultrasound imaging enhances the acute care provider's ability to evaluate, diagnose, and treat patients requiring emergency care. Currently, such bedside ultrasound imaging is generally confined to the scope of practice of emergency physicians. The American College of Emergency Physicians (ACEP) endorses the use of ultrasound imaging by emergency physicians in clinical situations that include: thoracoabdominal trauma; ectopic pregnancy; abdominal aortic aneurysm; pericardial effusion; and determining cardiac activity (1).

Focused ultrasound examination allows much needed insight into medical and trauma pathology that is not reliably detected by physical exam. In the acute care setting, ultrasound imaging yields valuable diagnostic information that can alter resuscitative

efforts in the acutely ill or injured patient. With improvement in ultrasound technology, portable devices are now being adapted to endure the rigors of the prehospital setting.

Trauma under triage contributes to higher patient mortality. Conversely, over triage is a significant cause of patient diversion to already overworked trauma centers. Multiple studies have confirmed the physical exam is insensitive at determining extent of injury. Considering the limitations of the physical exam, paramedics are severely hampered in their ability to determine severity of injury in the prehospital setting. A focused assessment with sonography in trauma (FAST) examination would provide the paramedic with a powerful tool for more accurate patient assessment.

The cardiac arrest patient often consumes a vast amount of resources in both the prehospital and hospital setting. It is often very difficult to determine the presence or absence of a peripheral pulse in the poorly perfusing cardiac patient. It has been found that pulseless electrical activity (PEA) is misdiagnosed in many cardiac arrest victims, and ultrasound allows for the determination between "true" PEA, a potentially reversible indication, and "pseudo" PEA, a fatal condition (2,3,4). It has also been shown that cardiac standstill diagnosed by ultrasound is 100% predictive of death (5). The ability of prehospital providers to make an accurate assessment of cardiac activity using ultrasound would improve resuscitative efforts in viable patients and allow for earlier termination of efforts in futile cases.

SPECIFIC AIMS

The purpose of this study is to determine whether previously trained EMS providers (EMT-Intermediate and Paramedics) can reliably perform and interpret cardiac and FAST ultrasound exams using portable ultrasound machines in critically ill or injured patients.

INCLUSION CRITERIA

There will be two targeted critically ill patient populations: medical and trauma

- Medical Patients: Only those medical patients in cardiac arrest will have an EMS cardiac ultrasound performed
- Trauma Patients: Only victims of significant blunt or penetrating trauma will be eligible for EMS FAST ultrasound examination

EXCLUSION CRITERIA

- Subjects aged less than 18 or older than 89 years will not be able to participate.
- Subjects who are not either in cardiac arrest (medical) or the victim of a significant traumatic injury mechanism (trauma).
- Patients may be excluded if the EMS provider feels the time taken to perform the US examination would provide ***any*** hinderance to provision of necessary medical or trauma care.

TIME FRAME

Training sessions and data analysis will be conducted over a 12-month period, from July 1, 2011 to June 30, 2012.

FUNDING

SonoSite Corporation, the company that manufactures portable ultrasound machines, significally supports this study. Please see attached "Budget" for more details.

STUDY DESIGN

This is a prospective observational trial, which rigidly maintains the current standard of care in critically ill cardiac arrest medical patients and critically injured trauma patients being transported by Norfolk EMS. All ultrasound (US) scans will performed by previously trained EMS providers as per EMS Educational Study (IRB# 09-11-EX-0212). During the previous study, EMS providers received a full day of ultrasound training, consisting of combination of didactics and hand-on ultrasound training, followed by an Observed Standard Clinical Examination (OSCE) to demonstrate mastery of the scanning protocols. All US examinations will be performed using the Sonosite M-Turbo portable US machine, an FDA approved medical device currently in use in healthcare settings across the world.

Medical Patients

Only medical patient in cardiac arrest are eligible for inclusion into the study. Medical patients in cardiac arrest will be treated according to regional TEMS protocols. Once the patient has been packaged into the EMS unit for transport, the cardiac ultrasound will be performed enroute to the receiving hospital, thus not prolonging on-scene time. The cardiac US examination will consist of at least a subcostal cardiac (SCC) view or a parasternal long axis (PSL) view, with both still images and a clip saved to the machine during the exam. No patient identifiers will be placed on the US images. The two primary

cardiac US data points to be obtained are: (1) presence or absence of organized cardiac activity and; (2) presence or abscess of a pericardial effusion with gross estimation of size (large or small). Upon arrival at the receiving facility, patient handoff to Emergency Department (ED) staff will proceed according to standard practice. Only after care has been safely handed off to ED staff will the EMS provider then complete the Data Collection Tool (see DCT) in the Study Packet. In addition, the EMS provider will download the images from the US machine onto a thumb drive and place the thumb drive into the study packet, which will then be placed into a locked box in the EMS reporting room at the receiving hospital. There will be absolutely no patient identifiers on the thumb drive US images and clips.

Trauma Patients

Only trauma patients with a significant traumatic mechanism (and thus potentially critically injured) are eligible for inclusion into the study. The trauma patients will be treated according to regional TEMS protocols without variance and will go to the trauma center according to the TEMS regional ambulance destination policy. Once the patient has been packaged into the EMS unit for transport, the FAST ultrasound examination will be performed enroute to the receiving hospital, thus not prolonging on-scene time. The FAST examination will consist of at least four views: (1) subcostal cardiac (SCC); (2) right lateral longitudinal (RLL); (3) left lateral longitudinal (LLL); and (4) transverse pelvis (TP) with both still images and a clips saved to the machine during the exam. No patient identifiers will be placed on the US images. The three primary FAST data points to be obtained are: (1) presence or absence of organized cardiac activity; (2) presence or abscess of a pericardial effusion with gross estimation of size (large or small); and (3) presence or absence of free intra-abdominal fluid. Upon arrival at the receiving facility, patient handoff to Emergency Department (ED) staff will proceed according to standard

practice. Only after care has been safely handed off to ED staff will the EMS provider then complete the Data Collection Tool (see DCT) in the Study Packet. In addition, the EMS provider will download the images from the US machine onto a thumb drive and place the thumb drive into the study packet, which will then be placed into a locked box in the EMS reporting room at the receiving hospital. There will be absolutely no patient identifiers on the thumb drive US images and clips.

Quality Assurance

In a timely fashion, all EMS performed US examinations will be reviewed by a Registered Diagnostic Medical Sonographer (RDMS) to determine both quality and accuracy of the scan. The EMS performed US will also be compared to the ultrasound examinations or computed tomography scans obtained during the patients ED or Trauma Bay care. We will also track any equipment issues.

DATA COLLECTION AND HANDLING

Please see the attached data collection tool (see DCT) for the data points that will be collected.

We will need to briefly retain the patient's medical record number or trauma number in order to obtain the official radiology attending reading of computed tomography (CT) scans or ultrasounds to compare with the EMS performed ultrasounds. We must have the gold standard by which to compare the prehospital studies. The gold standard in the trauma patient is the computed tomography scan obtained routinely in the trauma bay. The gold standard for the cardiac arrest patient is the attending Emergency Physician performed cardiac ultrasound in the Emergency Department. The medical record number and/or trauma number is impossible to link back to patients without being able to log in to the secure electronic medical record (EMR). All activity within the EMR is tracked by Sentara's

IT department, and unauthorized access of PHI can be identified and tracked to individual login codes. When EMS enrolls a subject, they will scan the study packet barcode, which will contain unique study numbers so that ultrasound images and patient information can be combined. We will obtain a patient ID sticker and place it on the study packet so that the bar code, images, and ED course can be reviewed retrospectively. Completed study packets will be then placed in a locked drawer.

Patients will be given the opportunity to opt out of study when safe to do so and within 72 hrs of enrollment. For subjects who are not able to make this decision, a research team member will try to contact a legally authorized representative (LAR) within 72 hrs. Once subject or LAR is informed of their involvement, they will be given the information letter that will give them the opportunity to opt out - of the use of the PHI. If the research team is unable to inform the subject or the LAR of their involvement, the data collected will still be used as the study only involves minimal risk.

We will destory the "sticker sheet" which will be the only link between the unique study number and the patient's medical record number as soon as final formal CT and ultrasound readings are obtained and entered into the secure database. Data will be entered into a secure database on a password-protected computer in the locked Department of Emergency Medicine office. Data sheets will be shredded after data entry has been accomplished. At the conclusion of the study, the Excel database will be destroyed. There will be no key kept after data entry into the database is complete, thus there will be no danger to the patient's PHI after data collection.

STATISTICS

At the conclusion of data collection, both descriptive and quantitative analysis of the data will be performed. We will report the overall quality of the EMS ultrasound examinations descriptively, and quantitatively describe the accuracy of the EMS US examination compared to the emergency department or trauma bay diagnostics using chi-square and student's t-test. If feasible, we will determine the Kappa Coefficient for inter-rater reliability between pre- hospital and physician performed FAST exams.

CONCLUSION

This is among the first large, city scale EMS ultrasound studies to be performed in the United States to determine the quality and accuracy of EMS provider ultrasound examinations in critically ill and injured patients. The authors believe this critical information will help guide care in future studies to provide a higher level of critical care in the field by our EMS providers, thus potentially reducing morbidity and mortality while simultaneously ensuring proper use of limited resources.

REFERENCES

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